

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

1. **Contracting Activity:** Veteran Health Administration (VHA), Service Area Office (SAO). The requesting facility is Department of Veterans Affairs, VISN 23, Minneapolis VA Healthcare System (MVAHCS) (618-14-2-652-0076)
2. **Nature and/or Description of the Action Being Processed:** SAO Central intends to negotiate on a sole source basis with the University of Minnesota (Minneapolis VAHCS's affiliate) Biomedical Genomics Center (BMGC – recently renamed to University of Minnesota Genomics Center [UMGC]).

The requesting facility Minneapolis VAHCS has a requirement with their Research Affiliate for various services in support of various research needs.

The proposed action is a sole source solicitation of a new contract with the University of Minnesota (Minneapolis VA's affiliate) The Biomedical Genomics Center. 1-210 Cancer & Cardiovascular Research Building 2231 6th Street SE Minneapolis, MN 55455. This acquisition allows the VA to establish or maintain an essential capability for research that, at present, cannot be performed at the Minneapolis VAHCS. The anticipated value of this requirement inclusive of base plus two option years for a total of \$220,824.36.

Time Requirement: 12 months from approval for the base year with the option of extending for two additional years.

**Project Period**

Base Year (12 months)

Option 1 (12 months)

Option 2 (12 months)

**Proposed costs:**

Base year- 12 months from approval--**\$73608.12**

**Option 1- \$73,608.12**

**Option 2- \$73,608.12**

This requirement is being requested under 38 U.S.C. 8153 (research with affiliates) to continue collaborative research services between the Minneapolis VA's Research Dr. Scott Sponheim, PhD and the University of Minnesota Biomedical Genomics Center.

This contract is being requested under 38 U.S.C. 8153. This contract will include a base year (12 months) plus two option years. The estimates are based on historical data and the most current information available.

### **3. Description of Supplies/Services Required to Meet the Agency's Needs**

The Minneapolis VAHCS/ Dr. Scott Sponheim, PhD requires expert health services associated with his current research study project, "Essential Features of Neural Damage in Mild Traumatic Brain Injury". This contract will ensure the delivery of services and the fulfillment of roles that otherwise cannot be filled. Services provided will include consultation on sample preparation for genotyping, tracking and handling the DNA specimens, application of a genotyping HumanCoreExome BeadChip from Illumina custom-designed by the Psychiatric Genomics Consortium (also known as the "PsychChip"; see <https://pgc.unc.edu>) to samples, and assistance in management, analysis, and interpretation of resulting genomic data. The genotyping work will specifically involve the purchase of reagents, amplification of DNA, use of bead technology to apply the Illumina chip, and organization and process of resulting quality control and genetic data. The PsychChip is available at a discounted price of \$45 per sample through the Biomedical Genomics Center and comprehensive services by the center are \$40 per sample, equaling a total of \$85 per sample for genome wide characterization of over 240,000 tagSNP markers, over 240,000 exome-focused markers, and 50,000 custom markers for psychiatric disorders.

The Minneapolis VAHCS/ Dr. Scott Sponheim, PhD requires expert health services associated with his current research study project "Essential Features of Neural Damage in Mild Traumatic Brain Injury". The University of Minnesota Biomedical Genomics Center is the premier center for genotyping work in the region. Dr. Sponheim has previously had genotyping services provided by the Biomedical Genomics Center and approves of the strong quality control procedures, thorough reports of genotyping results, management of specimens, analytic assistance, and availability of center staff for consultation and questions. The facility hosts the necessary instrumentation and computational resources to carry out high through-put genotyping of notable quality. Prior work with the center has resulted in very high quality genotype information. Additionally, the proximity of the Biomedical Genomics Center to the Minneapolis VA HCS allows Dr. Sponheim's staff to personally deliver and track specimens and to visit the BMGC for consultation and evaluation of the contracted work.

### **4. Statutory Authority Permitting Other than Full and Open Competition:**

- ☐ (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- ☐ (2) Unusual and Compelling Urgency per FAR 6.302-2;
- ☐ (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- ☐ (4) International Agreement per FAR 6.302-4
- ☒ (5) Authorized or Required by Statute FAR 6.302-5;
- ☐ (6) National Security per FAR 6.302-6;
- ☐ (7) Public Interest per FAR 6.302-7;

In accordance with FAR 6.302-5; the proposed acquisition strategy is consistent with legal precedence for sole sourcing research related affiliate contracts IAW 38. U.S.C. 8153.

38 U.S.C. 8153(a)(3)(A) provides:

"If the healthcare resource required is a commercial service, the use of medical equipment or space, or research, and is to be acquired from an institution affiliated with the Department in accordance with section 7302 of this title, including medical practice groups and other entities associated with affiliated institutions, blood banks, organ banks, or research centers, the Secretary may make arrangements for acquisition of the resource without regard to any law or regulation (including any Executive order, circular, or other administrative policy) that would otherwise require the use of competitive procedure for acquiring the resource."

**5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

The new contract is necessary to support Dr. Scott Sponheim, PhD "Essential Features of Neural Damage in Mild Traumatic Brain Injury" project. Because of the high level of specialized research involved with the proposed work the Biomedical Genomics Center is the premier center for genotyping work at the University of Minnesota. The facility hosts the necessary instrumentation and computational resources to carry out high through-put genotyping of high quality. Prior work with the center has resulted in very high quality genotype information. Specifically, Dr. Sponheim has previously had genotyping services provided by the Biomedical Genomics Center and approves of the strong quality control procedures, thorough reports of genotyping results, management of specimens, analytic assistance, and availability of center staff for consultation and questions. Additionally, the proximity of the Biomedical Genomics Center to the Minneapolis VA HCS allows Dr. Sponheim's staff to personally deliver and track specimens and to visit the BMGC for consultation and evaluation of the contracted work.

The Biomedical Genomics Center operates a complete instrumentation suite for Illumina Infinium Beadchip processing, including the Illumina Infinium automation system (Tecan robotics), the Illumina iScan scanner with robotic Beadchip loading carousel, and the Illumina GenomeStudio analysis platform running on a high-end PC with adequate RAM to load very large-scale GWAS studies. The Biomedical Genomics Center has over ten years of genomic-scale genotyping experience using a variety of platforms, from uniplex (Taqman), low-density (Sequenom iPLEX), high-density (Illumina GoldenGate and iSelect), to genome-wide platforms (Illumina Infinium platforms such as Omni). The Center has genotyped in excess of 305,000 samples over the past five years. It contains deep experience with Illumina Infinium genotyping, having processed in excess of 20,000 samples, including 7500 samples on ultra-high density Illumina methylation and genotyping chips. In addition to dozens of University of Minnesota researchers who use our services, our clients include over 400 external Principal Investigators from across the United States and overseas. The Biomedical Genomics Center operates an industrial-scale, SOP-driven set of processes, guided by a paper-less custom LIMS system for sample and document tracking, workflow management, and oversight of project planning and operations. It is hierarchically structured, with an Operations Manager for each of the three physical labs, overseeing project managers responsible for each individual project. For Illumina, the Biomedical Genomics Center maintains completely separate pre- and post-PCR laboratories.

Minneapolis VA and Research PI Dr. Scott Sponheim, PhD maintains an ongoing collaboration with and the University of Minnesota in an effort to provide veterans with the best possible care. The University of Minnesota has collaborated with the VA on past research studies and understands the unique needs of the veteran population and the delivery of healthcare services to veterans. The University of Minnesota has trained research personnel, statisticians, educational programmers, computer programmers, and data base managers who perennially complete innovative and groundbreaking research projects. Faculty at the University of Minnesota include nationally and internationally recognized physician, scientists, psychologists, statistical programmers and clinical specialists. Accordingly, because of their services, fair market costs, proximity and existing relationship with Minneapolis VAHCS, the University of Minnesota is capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

6.302(a)(2)(i) Full and open competition need not be provided for when a statute expressly authorizes or requires that the acquisition be made through another agency or from a specified source. In accordance with 38 U.S.C. 8153 (a)(3)(A) an FBO notice will not be posted as this is a

service directly related to research with an affiliate.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

The University of Minnesota Department Biomedical Genomics Center is a not-for-profit organization affiliated with The University of Minnesota. There is a clear pricing used in determining if the current pricing is fair and reasonable. The PsychChip is available at a discounted price of \$45 per sample through the Biomedical Genomics Center and comprehensive services by the center are \$40 per sample, equaling a total of \$85 per sample for genome wide characterization of over 240,000 tagSNP markers, over 240,000 exome-focused markers, and 50,000 custom markers for psychiatric disorders (processing roughly 850 samples as well as +8 CEPH DNA controls). The previous contract from the University of MN for this service was based on these rates (VA263-15-P-0725 07/25/2015 – 07/26/2016 total charge of \$73,608 for 865 units).

The Contracting Officer anticipates the price noted above to be fair and reasonable in comparison with past contracts.

Price negotiations may be conducted if the CO determines this is necessary.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

University of Minnesota is an affiliate and collaborative research partner of the Minneapolis VAHCS. 38 U.S.C. 8153 allows for sole source awards related to research services with affiliates. Because of the high importance of maintaining physical control of specimens it is necessary to locally provide the genotyping services. Nonetheless, the same Illumina chip (but without required customization for mental disorders) costs approximately \$80 per sample from other vendors and full service sample processing and data management runs \$250 per specimen which is 388% more expensive than the pricing offered through the Biomedical Genomics Center for the customized PsychChip not available through other vendors.

The VIP database was searched for available SDVOSB and VOSB vendors. Several vendors were found under the key word "research", but none of them proved to be viable resources for genotyping research specifically.

**9. Any Other Facts Supporting the Use of Other than Full and Open Competition**

The mission of the Department of Veterans Affairs is to discover knowledge and create innovations that advance health care for our Veterans and the nation.

VHA is the country's largest integrated health care system and as such it embraces close ties with academic affiliates by partnering on common research interests to leverage resources and expand the impact of federal research investments to assist our nations Veterans. Minneapolis VAHCS is one of the many examples of this strategic affiliate relationship recognized by the Secretary, Department of Veterans Affairs.

Several collaborative research projects are being carried out between the University of Minnesota and the Minneapolis VAHCS. This arrangement is mutually beneficial and highly cost effective in regard to the use of facilities and resources.

**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

As this is an affiliate contract, there are no actions that can be taken to remove or overcome any barriers to competition.

**11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**

Given the unique nature of this requirement and the collaborative nature of the research work being conducted services must continue to be met through the sole source provisions of 38 U.S.C. 8153 and FAR 6.302-5.

**12. Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

2/2/2015

X Brian Conley

Brian Conley  
Program Specialist, COR  
Signed by: Brian P Conley 606319

2/2/15 Date

**1. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

- a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Phillips, Pamela P.

Digitally signed by Phillips, Pamela P.  
DN: dc=gov, dc=va, ou=Entities, ou=InternalStaff,  
cn=Phillips, Pamela P.  
Date: 2016.07.21 08:30:29 -06'00'

Pamela Phillips  
Contract Specialist  
Black Hills Health Care System NCO 23

Date

- b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Daryl A. Berg 429170

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ou=2342, 1.9.2342.19200300.100.1.1=daryl.berg@va.gov,  
cn=Daryl A. Berg 429170  
Date: 2016.07.19 15:27:14 -05'00'

7/19/2016

Daryl Berg  
NCO' 23 Director of Contracting or Designee

Date